Oncology Nursing Society

125 Enterprise Drive
Pittsburgh, PA 15275-1214
412-859-6100
412-859-6161 - fax
government.relations@ons.org
www.ons.org - ONS Online

September 12, 2005

The Honorable Candice Miller
Chairwoman
Subcommittee on Regulatory Affairs
House Government Reform Committee
US House of Representatives
Washington, DC 20515

Dear Chairwoman Miller:

On behalf of the Oncology Nursing Society (ONS) — the largest professional oncology group in the United States composed of more than 33,000 nurses and other health professionals which maintains a long-standing commitment to promoting excellence in oncology nursing, teaching, research, administration, education in the field of oncology, and the provision of quality care to individuals affected by cancer — we respectfully submit these written comments to your subcommittee to be part of the official record for the September 13th field hearing in Boston, *"OxyContin and Beyond: Examining the Role of FDA and DEA in Regulating Prescription Painkillers."*

As part of its mission, the Society stands ready to work with policymakers at the local, state, and federal levels to advance policies and programs that will reduce and prevent suffering from cancer, including initiatives that improve pain and symptom management and enhance quality-of-life. To that end, ONS commends you and your subcommittee colleagues for recognizing the importance of examining the role of the Food and Drug Administration (FDA) and the Drug Enforcement Agency (DEA) in regulating prescription painkillers. We thank you for the opportunity to submit these written comments and discuss the importance of appropriate regulation of, access to, and use of controlled substances for the treatment of cancer related pain.

Under-treated Pain – A Major Public Health Problem

Pain is a major health problem in the United States, especially the kind of pain that is often experienced by individuals with cancer. The treatment and management of pain and accompanying symptoms such as fear, anxiety, depression, weakness, nausea, and vomiting need to be improved significantly. When pain is severe, it interferes with activities and quality-of-life; diminishing physical, psychological, and interpersonal well-being. It is perhaps one of the more tragic realities in health care today that, despite the existence of many drugs and

techniques for treating pain, countless individuals continue to suffer needlessly from unrelieved pain.

Greater emphasis on quality-of-life for individuals at end-of-life and the growth of hospice care in this country have done much to validate the role of opiates in treating pain and suffering. Although considerable progress has been made to improve the adequate treatment of pain through efforts at educating health care professionals and the public, still less than half of patients with cancer get adequate relief of their pain and approximately one in four patients with cancer die with unrelieved pain. Much of the failure to relieve cancer-pain stems from patient, provider, and family misconceptions and fears. Moreover, recent controversies and negative media attention regarding the use of opiates have begun to erode much of the progress that has been achieved in this arena. It is, indeed, an unfortunate reality that the class of drugs that has the potential to alleviate pain and suffering also has the potential to be abused. Adequate pain control further is complicated by regulatory agencies that scrutinize professional licensure and restrictively regulate controlled substances — practices that are well-intended but unintentionally can obstruct legitimate use rather than stem diversion. However, while it is essential to strike a delicate balance between legitimate access and efforts to prevent diversion and abuse, it is critical to note that there is abundant evidence that the vast majority individuals — including people with cancer — who use these drugs for their legitimate and intended purposes, do not go on to abuse them.

Under-managed pain often results in emotional and economic consequences both of which have long term costs to affected individuals and their families. Therefore, it is essential that improved quality-of-life through expert pain control be available to all who experience pain, not just a select class of patients with specific diagnosis. More must be done to ensure that appropriate pain management is the standard of care for the young as well as the elderly, and for those with chronic illness or at end-of-life. ONS believes that the inadequate treatment of pain is a significant public health problem in the United States and requires the necessary public health response.

Cancer-related Pain

While we have made significant gains in cancer survival rates, unfortunately each year another 1.3 million Americans will receive a cancer diagnosis and more than 570,000 Americans will lose their battle with this terrible disease. For these individuals and their families, it is essential that we take all the steps necessary to ensure that throughout their treatment — and through survivorship or end-of-life, that their pain and other symptoms are managed appropriately. Moreover, as cancer risk increases with age, so do the risk and incidence of other chronic conditions. Therefore, many who develop cancer also suffer from other co-morbidities and underlying painful conditions associated with their other health problems such as arthritis, diabetes, or prior trauma.

Additionally, concurrent advances in the treatment of cancer have yielded a growing population of patients who are living longer with cancer as well as an increased number of people who are cured and transition to cancer "survivorship." Many of those patients who live

long-term continue to experience pain that may be related to their treatment rather than the malignancy itself. These patients often suffer moderate to severe pain on a daily basis which compromises their ability to function in various life activities. Therefore, this cohort has more in common with the non-malignant pain patient than the patient who has pain associated with advancing disease. For example, pain may be due to nerve injury or scar tissue formation from cancer-related surgical intervention. As such, ONS advocates increasing access to — and ensuring the availability of — quality, comprehensive pain and symptom management, psycho-social support, follow-up, and end-of-life care for people with cancer.

Opioid Treatment Essential to Managing Cancer-related Pain

Cancer patients typically have two types of pain — continuous, persistent pain that is always present and intermittent or breakthrough pain that occurs with activity. While surgery, radiation, and chemotherapy may be used to control the pain by shrinking the cancerous tumor, drugs such as non-opioids, opioids, and adjuvant medications are the mainstay of pain treatment. For years, morphine has been the standard opioid of comparison to treat severe pain in cancer patients. However, as knowledge about pain physiology and pharmacology translates into better analgesics or new formulations of opioids with fewer side effects, morphine has not remained the drug of choice. Morphine has several active metabolites including morphine 6-glucuronide and morphine 3-glucuronide that may accumulate in patients with renal disease, renal dysfunction, or elderly persons because of decreased clearance and prolonged elimination half-life. When this occurs, patients taking morphine may become confused, disoriented, sedated, and may experience other side effects. Because of these problems related to morphine's active metabolites, the trend has been to use semisynthetic opioids such as oxycodone, fentanyl, and hydromorphone.

People with cancer usually need to be treated with continuous release opioids (usually dosed twice a day) for the persistent pain and short acting opioids (usually dosed every two to four hours) for the breakthrough pain. At present the only continuous release opioids that are available are morphine (MS Contin®, Oramorph®, Kadian®), oxycodone (OxyContin®), and fentanyl (Duragesic patch® typically dosed every 72 hours). Some cancer patients cannot tolerate morphine because of side effects of nausea and vomiting while others need to take high doses of continuous release oxycodone because they are not able to use the fentanyl patch as they would need multiple patches to equal the OxyContin® dose they are taking. With the availability of controlled release oxycodone, cancer patients are able to have access to another analgesic for relief of persistent pain. If access to opioids, such as OxyContin®, were to be restricted severely, such a limitation could pose a major problem — and threat to health and well-being — not only for people with cancer but a multitude of patients with chronic nonmalignant pain who are enjoying an improved quality-of-life because of OxyContin®.

Risk Management, Diversion Control, Abuse Prevention, and Legitimate Access: A Delicate But Necessary Policy Balance

ONS maintains a long-standing commitment to ensuring that all people with cancer-related pain have access to the quality pain and symptom management care, services, and therapies

they need and deserve. Specifically, our organization believes that all people with legitimate need must be assured access to the medication and therapies that they and their health care providers deem most appropriate. We recognize and appreciate that with the potential for abuse, our nation must develop and implement appropriate, yet reasonable practices and regulations to ensure that these drugs do not fall into the wrong hands and are not abused.

As you may know, ONS is one of 21 national organizations that lent its support in 2001 for the "Joint Consensus Statement" on "*Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act*" articulating the need for balance between the treatment of pain and enforcement against diversion and abuse of prescription medications. This important document reflects a consensus among myriad health care providers, patient advocates, and law enforcement agencies that the prevention of drug abuse is an important public health and societal goal that can — and should — be pursued without impeding appropriate patient care.

As the Joint Consensus Statement asserts, "Effective pain management is an integral and important aspect of quality medical care, and pain should be treated aggressively." Moreover, the Joint Consensus Statement also recognizes that, "Focusing only on the abuse potential of a drug, however, could erroneously lead to the conclusion that these medications should be avoided when medically indicated — generating a sense of fear rather than respect for their legitimate properties."

Clearly, there are classes of drugs that should be regulated in an appropriate fashion so as to prevent and reduce diversion and abuse. However, in these important efforts, we must not increase the burden to patients or the health care professionals who are administering their pain-related care. Regulations that limit reliance on professional clinical judgment and unduly restrict access encumber the provision and delivery of appropriate pain management for patients with legitimate needs.

The percentage of the population who take prescription drugs for non-medical purposes has remained stable for the last decade at 1-1.5 percent as has the percentage of the population with an illicit drug problem (6-7 percent). This suggests that while periodic hotspots develop around a particular drug in certain communities, overall our nation's policies are working to minimize drug abuse. To that end, a study of opioid use and abuse published in the Journal of the American Medical Association concluded that the increase in medical use of opioid analgesics does not contribute to the increase in abuse.[1] However, we unfortunately always have had to be aware that an individual's request for a certain drug could be based in real need/response but also could be based on its street value. Yet, as noted above, we continue to see significant numbers of people with cancer dying in pain. This indicates that while our policies work to stem the tide of abuse they may be standing in the way of providing legitimate and necessary quality care for those in need. ONS agrees that drug abuse is a serious problem and that its prevention is an important societal goal; yet, ONS maintains — as stated in the Joint Consensus

[1] Data from 1990-96), Joransen DE, Ryan KM, Gilson AM, Dahl JL. Trends in medical use and abuse of opioid analgesics. JAMA 2000; 283(13):1710-1714.

Statement — that [efforts to prevent drug abuse] "should not hinder patients' ability to receive the care they need and deserve."

ONS Recommendations

As part of our nation's ongoing effort to minimize diversion and abuse, nurses monitor the effects of controlled substances — including positive and negative effects, screen for drug use and abuse in daily practice, and make referrals when appropriate. Oncology nurses have been leaders in providing pain education and our organization provides education to our members through our journals, at conferences, and at special events. Nurses are experts in developing patient educational materials and work to teach patients how to manage their opioids, including safety issues. Moreover, nurses collaborate in teaching children in their community about drug abuse.

To augment and enhance these efforts, we feel strongly about the need for improved educational efforts that include how to stop drug diversion, how to keep records, and how to document proper assessment and prescription distribution. Specifically, health care professionals need access to education and training regarding pain control, especially with respect to the safe and appropriate use of opiates. Education and support are essential for health care professionals who prescribe and monitor patients using opiates in order to counter the intimidation that is often felt in the current climate where so much attention is focused on stemming diversion and abuse. Such education must include law enforcement, physicians, nurses, and pharmacists and should involve the national organizations representing these professionals (e.g. National Association of State Controlled Substance Authorities and National Association of Drug Diversion Investigators). These educational initiatives must focus equally on legitimate pain management and prevention of diversion and abuse. Unfortunately, many of the individuals and entities currently engaged in efforts relating to prescription drug abuse do not have a comprehensive understanding or perspective of the nature of pain and the associated therapies.

ONS believes that steps can be taken to prevent diversion and abuse while promoting access to opiates for legitimate pain relief. We respectfully encourage your subcommittee, the DEA, the FDA, and other relevant and appropriate federal agencies to address the critical issues of pain management and barriers to quality pain and symptom management as opposed to focusing solely on a particular therapeutic agent. Without a comprehensive understanding and evaluation of the status of the nation's current pain management delivery system, the potential unintended adverse repercussions of changing federal regulatory policy related to one drug could lead to fear and diminished access to care among those with legitimate needs. To that end, ONS recommends that the federal government:

1. Establish and maintain an ongoing dialogue between the DEA, the FDA, and health care professionals to encourage cooperation and mutual understanding in an effort to ensure a balanced and rational approach to effective symptom management and minimization of illicit drug use;

2. Work with health care professionals to develop guidelines for practice that will assure access to opiates based on sound clinical judgment and patient need, while increasing early recognition of problem behaviors;
3. Develop educational materials for patients and family members that will reassure them of the legitimacy of opiates in treating pain while giving them guidelines for safe use and the prevention of diversion or abuse;
4. Allocate resources to educate health professionals about the appropriate use of opiates and associated pain management techniques, both pharmacological and non-pharmacological;
5. Support projects aimed at identifying and eliminating system-level obstacles that preclude effective pain management in acute pain, cancer pain, and chronic pain; and
6. Assure that federal publications delineate clearly between substance abuse and legitimate pain management in acute pain, cancer pain, and chronic pain as the evidence that addiction is very rare in patients who have pain should be acknowledged more widely.

Summary

On behalf of ONS and our members who are involved in the provision of cancer-related pain and symptom management, we thank the Subcommittee for its consideration of our views on this important public health matter. ONS affirms its commitment to promoting the relief of cancer-related pain and suffering and urges the Subcommittee — as well as the FDA and the DEA — to consider first and foremost, the needs of those who suffer needlessly from unrelieved pain and to take steps to assure their continued access to the pain relief they need and deserve.

Please know that the Society stands ready to work with your subcommittee, the DEA, the FDA, and Congress to achieve our mutual goal of preventing diversion and abuse of pain therapies while also ensuring that patients with legitimate pain continue to have access to quality, appropriate, and legitimate relief. If we can be of any assistance to you, or if you have any questions, please feel free to contact us or our Washington, DC Health Policy Associate, Ilisa Halpern (202/230-5145, ihalpern@gcd.com).

Sincerely,

Karen J. Stanley

Karen Stanley, RN, MSN, AOCN®, FAAN
President

Pearl Moore

Pearl Moore, RN, MN, FAAN
Chief Executive Officer